

Bill No. SB 468

Barcode 740844

CHAMBER ACTION

Senate

House

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The Committee on Health Care (Miller) recommended the following amendment:

Senate Amendment (with title amendment)

Delete everything after the enacting clause

and insert:

Section 1. Paragraph (h) of subsection (1) of section 20.435, Florida Statutes, is amended to read:

20.435 Department of Health; trust funds.--

(1) The following trust funds are hereby created, to be administered by the Department of Health:

(h) Biomedical Research Trust Fund.

1. Funds to be credited to the trust fund shall consist of funds deposited pursuant to ss. ~~s.~~ 215.5601, 288.955, and 381.99. Funds shall be used for the purposes of the James and Esther King Biomedical Research Program as specified in ss. 215.5602 and 288.955 and the purposes of the Florida Better Quality of Life and Biomedical Research Act as specified in s. 381.99. The trust fund is exempt from the service charges imposed by s. 215.20.

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1 2. Notwithstanding the provisions of s. 216.301 and
 2 pursuant to s. 216.351, any balance in the trust fund at the
 3 end of any fiscal year shall remain in the trust fund at the
 4 end of the year and shall be available for carrying out the
 5 purposes of the trust fund. The department may invest these
 6 funds independently through the Chief Financial Officer or may
 7 negotiate a trust agreement with the State Board of
 8 Administration for the investment management of any balance in
 9 the trust fund.

10 3. Notwithstanding s. 216.301 and pursuant to s.
 11 216.351, any balance of any appropriation from the Biomedical
 12 Research Trust Fund which is not disbursed but which is
 13 obligated pursuant to contract or committed to be expended may
 14 be certified by the Governor for up to 3 years following the
 15 effective date of the original appropriation.

16 4. The trust fund shall, unless terminated sooner, be
 17 terminated on July 1, 2008.

18 Section 2. Present subsections (2), (3), (4), and (5)
 19 of section 381.86, Florida Statutes, are renumbered as
 20 subsections (3), (4), (5), and (6), respectively, and a new
 21 subsection (2) is added to that section, to read:

22 381.86 Institutional Review Board.--

23 (2) The Secretary of Health shall determine and
 24 appoint the membership of the board and designate its chair,
 25 except with respect to a review of research funded under s.
 26 381.99 which shall have a separate review committee
 27 constituted as described in s. 381.99 for the sole purpose of
 28 reviewing research funded under s. 381.99.

29 Section 3. Section 381.99, Florida Statutes, is
 30 created to read:

31 381.99 Florida Better Quality of Life and Biomedical

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1 Research Act.--

2 (1) SHORT TITLE.--This section may be cited as the
3 "Florida Better Quality of Life and Biomedical Research Act."

4 (2) DEFINITIONS.--As used in this section, the term:

5 (a) "Adult stem cell" means an undifferentiated cell
6 found among differentiated cells in a tissue or an organ that
7 can renew itself and can differentiate to yield the major
8 specialized cell types of the tissue or organ.

9 (b) "Embryonic stem cells" means cells obtained from
10 the undifferentiated inner mass of an early stage embryo.

11 (c) "Human reproductive cloning" means the practice of
12 creating or attempting to create a human being by transferring
13 the nucleus from a human cell into an egg cell from which the
14 nucleus has been removed for the purpose of implanting the
15 resulting product in a uterus or substitute for a uterus to
16 initiate a pregnancy.

17 (d) "In vitro fertilization" means a technique in
18 which oocytes are fertilized by sperm outside of a woman's
19 body resulting in organisms that are not genetically identical
20 to any one existing human.

21 (e) "Stem cells" means undifferentiated cells which
22 retain the potential to differentiate into some or all other
23 cell types.

24 (3) LEGISLATIVE FINDINGS.--The Legislature finds that:

25 (a) An estimated 130 million Americans suffer from
26 acute, chronic, and degenerative diseases and that there is
27 enormous potential for lifesaving treatment and therapy as a
28 result of recent advances in biomedical research.

29 (b) Florida is unique among all states for its large
30 projected net population increase within the next 20 years.
31 This increase, in turn, raises significant health care

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1 concerns as a new, larger generation of retirees moves to this
 2 state, resulting in a corresponding rise in the number of
 3 persons suffering from illnesses such as cancer, heart
 4 disease, Alzheimer's Disease, Parkinson's Disease, cerebral
 5 palsy, atherosclerosis, amyotrophic lateral sclerosis, AIDS,
 6 spinal cord injuries, severe burns, osteoporosis,
 7 osteoarthritis, cystic fibrosis, muscular dystrophy, multiple
 8 sclerosis, macular degeneration, diabetic retinopathy,
 9 retinitis pigmentosa, cirrhosis of the liver, motor neuron
 10 disease, brain trauma, stroke, sickle cell anemia, and
 11 intestinal diseases. Juvenile diabetes is becoming more
 12 prevalent in children in this state.

13 (c) In order to maintain a high quality of life for
 14 all Floridians, research into stem cell regenerative therapies
 15 and treatment, among other therapies and treatments, should be
 16 supported to give hope and relief to the millions of residents
 17 who suffer in silence from degenerative and crippling
 18 diseases.

19 (d) To reduce the burden on the health care
 20 infrastructure, the state must shift its health care
 21 objectives from costly long-term maintenance toward prevention
 22 and cures.

23 (e) To bolster and advance Florida's burgeoning
 24 biotechnology industry, the state should continue to provide
 25 funds and incentives for private research companies to work in
 26 the state.

27 (f) The state should advance the goal of scientific
 28 and academic discourse in our colleges, universities, and
 29 private research institutions and should continue to help
 30 bring these institutions to the forefront in biomedical
 31 research and technology.

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1 (g) It will benefit the economy of the state to create
2 a wide array of new projects and high-paying jobs relating to
3 biomedical research.

4 (h) It will benefit the state to foster cooperation
5 between the state's colleges, universities, and private-sector
6 research in terms of jobs, resources, and academic discourse
7 relating to biomedical research.

8 (i) The public funds provided under this section are
9 intended to spur innovation and development in the state's
10 biomedical technology sector, which will be used to treat
11 debilitating chronic diseases.

12 (4) STEM CELL RESEARCH ADVISORY COUNCIL.--There shall
13 be established a Stem Cell Research Advisory Council.

14 (a) The advisory council shall consist of the
15 Secretary of Health, who shall act as chair, and six
16 additional members, who shall be appointed as follows:

17 1. Two persons appointed by the Governor, one of whom
18 shall be an academic researcher in the field of stem cell
19 research and one of whom shall have a background in bioethics.

20 2. One person appointed by the President of the
21 Senate, who shall have a background in private sector stem
22 cell funding and development and public sector biomedical
23 research and funding.

24 3. One person appointed by the Speaker of the House of
25 Representatives, who shall have a background in private-sector
26 stem cell funding and development and public-sector biomedical
27 research and funding.

28 4. One person appointed by the Minority Leader of the
29 Senate, who shall have a background and experience in
30 public-sector or private-sector stem cell research and
31 development.

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1 5. One person appointed by the Minority Leader of the
2 House of Representatives, who shall have a background and
3 experience in business and financial investments.

4
5 Members shall be appointed to terms of 2 years each commencing
6 on October 1, 2006. A member may not serve for more than two
7 consecutive 2-year terms. All initial appointments must be
8 made by October 1, 2006. The first meeting shall take place no
9 later than November 1, 2006. Members shall meet at least twice
10 annually, but no more than four times annually. Members shall
11 serve without compensation but are entitled to reimbursement
12 for per diem and travel expenses in accordance with s.
13 112.061.

14 (b) The members of the advisory council shall work to
15 provide an environment fostering the advancement of embryonic
16 and human adult stem cell research. The advisory council
17 shall:

18 1. Develop a donated-funds program for recommendation
19 to the Secretary of Health, to encourage the development of
20 funds other than state appropriations for embryonic and human
21 adult stem cell research in the state.

22 2. Examine and identify specific ways to improve and
23 promote for-profit and not-for-profit embryonic and human
24 adult stem cell and related research in the state, including,
25 but not limited to, identifying both public and private
26 funding sources for such research, maintaining existing
27 activities related to embryonic and human adult stem cell
28 research, recruiting new activities to the state related to
29 embryonic and human adult stem cell research, and recruiting
30 scientists and researchers in such fields to the state and
31 state universities.

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1 3. Develop a biomedical research grant program for
 2 recommendation to the Secretary of Health, which shall provide
 3 grants-in-aid to eligible institutions for the advancement of
 4 embryonic or human adult stem cell research.

5 4. Develop, no later than December 1, 2006, an
 6 application for grants-in-aid under this section for
 7 recommendation to the Secretary of Health for the purpose of
 8 conducting embryonic or human adult stem cell research.

9 5. Receive applications from eligible institutions for
 10 grants-in-aid on and after December 1, 2006, and provide to
 11 the Secretary of Health recommended grant awards.

12 6. Monitor the stem cell research conducted by
 13 eligible institutions that receive such grants-in-aid.

14 (c) The advisory council shall submit an annual
 15 progress report on the state of biomedical research in the
 16 state to the Florida Center for Universal Research to
 17 Eradicate Disease and to the Governor, the Secretary of
 18 Health, the President of the Senate, and the Speaker of the
 19 House of Representatives by June 30. The report must include:

20 1. The amount of grants-in-aid awarded to eligible
 21 institutions from the Biomedical Research Trust Fund.

22 2. The recipients of such grants-in-aid.

23 3. The current status and progress of stem cell
 24 research in the state.

25 4. A list of research projects supported by
 26 grants-in-aid awarded under the program.

27 5. A list of publications in peer-reviewed journals
 28 involving research supported by grants-in-aid awarded under
 29 the program.

30 6. The total amount of biomedical research funding
 31 currently flowing into the state.

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1 7. New grants for biomedical research that were funded
2 based on research supported by grants-in-aid awarded under the
3 program.

4 8. All other materials the council deems advisable to
5 include.

6 (d) Advisory council members shall disclose any
7 conflict of interest or potential conflict of interest to the
8 Secretary of Health.

9 (e) The Department of Health shall provide
10 administrative staff to assist the advisory council in
11 developing the application for the grants-in-aid, reviewing
12 such applications, making recommendations to the advisory
13 council, preparing the written consent form described in
14 paragraph (7)(b), and performing other administrative
15 functions as the advisory council requires or as is deemed
16 necessary.

17 (5) STEM CELL ETHICS INSTITUTIONAL REVIEW
18 BOARD.--There shall be established within the Institutional
19 Review Board of the Department of Health a separate committee
20 that shall have oversight of the research conducted pursuant
21 to s. 381.99. The board shall provide ethical oversight for
22 stem cell research.

23 (a) For this committee only, there shall be seven
24 members, of which the Secretary of Health or the secretary's
25 designee shall act as chair. The additional members shall be
26 recommended to the secretary for appointment as follows:

27 1. Two persons appointed by the Governor.

28 2. One person appointed by the President of the
29 Senate.

30 3. One person appointed by the Speaker of the House of
31 Representatives.

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1 4. One person appointed by the Minority Leader of the
2 Senate.

3 5. One person appointed by the Minority Leader of the
4 House of Representatives.

5
6 All members must demonstrate knowledge and understanding of
7 the ethical, medical, and scientific implications of embryonic
8 and adult stem cell research and should also demonstrate
9 knowledge of related fields, including, but not limited to,
10 genetics, cellular biology, and embryology. At least three
11 members shall have practical research experience in stem cell
12 research or related fields. Members shall be appointed to
13 terms of 4 years each commencing on October 1, 2006. A member
14 may not serve for more than two consecutive 4-year terms. All
15 initial appointments must be made by October 1, 2006. The
16 first meeting shall take place no later than November 1, 2006.
17 Members shall meet at least twice a year or as often as
18 necessary to discharge their duties but have no more than one
19 meeting per month during any 12-month period. Members shall
20 serve without compensation but are entitled to reimbursement
21 for per diem and travel expenses in accordance with s.
22 112.061.

23 (b) The committee shall review all embryonic or human
24 adult stem cell research that is funded or supported in any
25 manner through the Biomedical Research Trust Fund to ensure
26 the adherence to ethical and safety guidelines and procedures
27 as laid out by federal ethical standards established by the
28 United States Department of Health and Human Services.

29 (6) BIOMEDICAL RESEARCH TRUST FUND AND
30 GRANTS-IN-AID.--

31 (a) The Secretary of Health shall make grants-in-aid

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1 from the Biomedical Research Trust Fund in accordance with the
2 provisions of this section.

3 (b) The Department of Health shall require any
4 applicant for a grant-in-aid under this section, for the
5 purpose of conducting stem cell research, to submit a complete
6 description of the applicant's organization, the applicant's
7 plans for stem cell research, the applicant's proposed funding
8 for such research from sources other than the state, and the
9 applicant's proposed arrangements concerning financial
10 benefits to the state as a result of any patent, royalty
11 payment, or similar rights resulting from any stem cell
12 research made possible by the awarding of such grant-in-aid.

13 The Stem Cell Research Advisory Council shall provide
14 recommendations to the Secretary of Health with respect to
15 awarding such grants-in-aid after considering recommendations
16 from the Stem Cell Ethics Institutional Review Board.

17 (c) Beginning with the 2006-2007 fiscal year, and for
18 10 consecutive years thereafter, not less than \$15 million
19 shall be made available annually from the Biomedical Research
20 Trust Fund for grants-in-aid to eligible institutions for the
21 purpose of conducting embryonic or human adult stem cell
22 research as directed by the Stem Cell Research Advisory
23 Council. Up to 15 percent of the funds may be used for
24 administrative costs. Any balance of such amount not used for
25 such grants-in-aid during a fiscal year shall be carried
26 forward for the fiscal year next succeeding for such
27 grants-in-aid.

28 (7) FUNDING.--Funds provided under this section may be
29 used only for research involving:

30 (a) Human adult stem cells, including, but not limited
31 to, adult stem cells derived from umbilical cord blood and

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1 bone marrow.

2 (b) Human embryonic stem cells taken from donated
3 leftover embryos from in vitro fertilization treatments which
4 would otherwise be thrown away or destroyed.

5 1. A physician or other health care provider who is
6 treating a patient for infertility shall provide the patient
7 with timely, relevant, and appropriate information sufficient
8 to allow the person to make an informed and voluntary choice
9 regarding the disposition of any human embryos that remain
10 following infertility treatment.

11 2. A person to whom information is provided pursuant
12 to subparagraph 1. shall be presented with the options of
13 storing any unused embryos, donating them to another person,
14 donating the remaining embryos for research purposes, or
15 selecting other means of disposition.

16 3. A person who elects to donate, for research
17 purposes, any embryos remaining after receiving in vitro
18 fertilization treatment shall provide written consent for that
19 donation in a consent form provided by the Department of
20 Health and made available to the public on the department's
21 Internet website.

22 4. A person may not knowingly, for material or
23 financial gain, purchase, sell, or otherwise transfer or
24 obtain, or promote the sale or transfer of, embryonic fetal
25 tissue for research purposes pursuant to this section.
26 Embryonic and adult stem cell material may be donated only for
27 research purposes with the informed consent of the donor. A
28 person who violates this subparagraph commits a felony of the
29 second degree, punishable as provided in s. 775.082, s.
30 775.083, or s. 775.084.

31 (8) HUMAN REPRODUCTIVE CLONING; PROHIBITION;

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1 PENALTIES.--

2 (a) A person may not knowingly:

3 1. Perform or attempt to perform human reproductive
4 cloning.

5 2. Participate or assist in an attempt to perform
6 human reproductive cloning.

7 3. Ship or receive for any purpose an embryo produced
8 by human reproductive cloning or any product derived from such
9 embryo.

10 (b) A person who violates paragraph (a) commits a
11 felony of the second degree, punishable as provided in s.
12 775.082, s. 775.083, or s. 775.084.

13 Section 4. The sum of \$15 million is appropriated
14 annually for the next 10 years from the General Revenue Fund
15 to the Biomedical Research Trust Fund for the purposes of the
16 Florida Better Quality of Life and Biomedical Research Act
17 pursuant to s. 381.99, Florida Statutes.

18 Section 5. This act shall take effect July 1, 2006.

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21 ===== T I T L E A M E N D M E N T =====

22 And the title is amended as follows:

23 Delete everything before the enacting clause

24

25 and insert:

26 A bill to be entitled
27 An act relating to biomedical research;
28 amending s. 20.435, F.S.; revising uses for
29 funds credited to the Biomedical Research Trust
30 Fund; amending s. 381.86, F.S.; providing that
31 the Institutional Review Board within the

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1 Department of Health may not review certain
2 research within the jurisdiction of the Stem
3 Cell Ethics Institutional Review Board;
4 creating s. 381.99, F.S., the Florida Better
5 Quality of Life and Biomedical Research Act;
6 providing definitions; providing legislative
7 findings; creating the Stem Cell Research
8 Advisory Council; providing for criteria,
9 appointment, and terms of members; authorizing
10 reimbursement for per diem and travel expenses;
11 providing duties of the advisory council,
12 including a report to the Governor, the
13 President of the Senate, and the Speaker of the
14 House of Representatives; requiring the
15 Department of Health to provide administrative
16 support; creating the Stem Cell Ethics
17 Institutional Review Board to regulate research
18 procedures and enforce ethical guidelines;
19 providing for criteria, appointment, and terms
20 of members; authorizing reimbursement for per
21 diem and travel expenses; providing duties of
22 the oversight council; providing for a
23 grants-in-aid program for the purpose of
24 conducting embryonic or human adult stem cell
25 research; providing that grants-in-aid shall be
26 provided through funds in the Biomedical
27 Research Trust Fund; restricting the use of
28 such funds for research on certain stem cells;
29 providing requirements with respect to the
30 disposition of human embryos following
31 infertility treatment; requiring the Department

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1 of Health to develop and maintain on its
2 Internet website a consent form for the
3 donation of certain embryos; prohibiting the
4 purchase or sale of embryonic fetal tissue for
5 research purposes; prohibiting certain acts
6 relating to human reproductive cloning;
7 providing penalties; providing an
8 appropriation; providing an effective date.

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